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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,370	12/21/2001	Jeffrey A. Trogolo	A-036	5277

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AGION TECHNOLOGIES
60 Audubon Road
Wakefield, MA 01880

EXAMINER	
EBRAHIM, NABILA G	
ART UNIT	PAPER NUMBER
1618	
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07/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/032,370	TROGOLO ET AL.	
	Examiner	Art Unit	
	NABILA EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/25/20096*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-22,33,34,45,48-51 and 53-64* is/are pending in the application.

4a) Of the above claim(s) *45,50,51,53 and 54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-22,33,34,48,49 and 55-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/2007 has been entered.

Status of Claims

Claims *1-7, 10-22, 33-34, 45, 48-51 and 53-64 are* pending in the application.

Claims 45, 50-51, and 53-54 are withdrawn from consideration.

Claims 1-7, 10-22, 33-34, 48-49 and 55-64 are under current examination.

Status of Office Action: Non-Final.

Election/Restrictions

Claims 45, 50-51, 53-54 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/31/2008.

Applicant's election with traverse of claims 1-7, 10-22, 33-34, 48-49 and 55-64 in the reply filed on 10/31/2008 is acknowledged. The traversal is on the ground(s) that the restriction requirement stating that the first element in assessing whether a restriction requirement is proper is a determination that the inventions are distinct. Although the Examiner alleges distinction, the undersigned is at a loss to understand the basis for the alleged distinction as set forth in Paragraph 2. The undersigned does not appreciate how the conclusory remark of that paragraph fits either of conditions (1) or (2), Hydrophobic polymers are a subset of the more

general polymer matrix. To clarify for Applicant, the distinction is made through option (2) and the product's release can be altered by comprising the antimicrobial additive in hydrophobic polymer or by incorporating the antimicrobial into a polymer matrix that can alter the release.

Applicant proceeds stating that even assuming for the moment that distinction had been established, the Examiner provides no particular reason or guidance as to which of the enumerated reasons apply for why the search and examination would be a serious burden. Hence, again the restriction requirement is improper or fails in that it is not properly established. To respond to applicant's argument, the form paragraph states that "Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply". In the instant case, at least "C" and "D" are particular reasons for restriction.

Applicant argues that there should not be search burden on the Examiner after the long period of prosecution. The Examiner's position was shown in the difference of the classification of the two inventions. Thus, it is noted that the search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, however, extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present two distinct inventions. It is noted that the restriction requirement is necessitated by amendment filed June 21, 2007 in an Request of Continuing Examination, second sentence states: "if the distinctness and independence of the invention is clear, such requirement will be made before any action

upon the merits however, it may be made at any time before final action in the case at the discretion of the examiner. Thus, the instant restriction requirement is considered to be proper in a timely manner.

Finally, in the response filed by Applicant dated 3/25/2009, Applicant argues that In applicants' response of June 21, 2007, all of the independent claims were amended to recite that the hydrophilic polymer was water absorbing, water vapor absorbing and wettable " so as to expedite allowance inasmuch as this amendment led to allowance of applicants' corresponding, co-filed and now issued patent no US 7,357,949. The undersigned has repeatedly suggested that the examiner review that file since it is similar to the present application and may help in bringing this case to conclusion.

To respond, it is noted that each application is treated on its own merits and according to its prosecution progress.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5-7 and 60-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite “ceramic carrier” and “zeolite carrier”. The specification describes a ceramic particle. Thus, the claim language is not clear since it does not explain if the zeolite is an alternative particle that is different from the hydrophilic polymer retaining the metal ion, or if the zeolite is a particle containing the hydrophilic polymer retaining the metal (like a coating) or finally if the zeolite is the

carrier (substrate or article) containing the hydrophilic polymer and the metal particle. The claims are ambiguous.

For the purpose of examining the claims, the Examiner will use the word "carrier as a substrate containing the antimicrobial hydrophilic polymer which is in turn retaining the metal ion.

Claim Rejections - 35 USC § 102

1. The rejection of claims 1-4, 10-12, 22, 33, 34, 48, and 49 under 35 U.S.C. 102(b) as being anticipated by Hagiwara et al. US 4775585 (Hagiwara) is hereby withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 10-18, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamaguchi Chiharu et al. JP 11-222402, machine translation (JP).

JP teaches an antibacterial resin composition in an antimicrobial polymer particle. The antibacterial metallic component is chemically combined with a polymer particle namely, a polymer particle which constitutes antimicrobial polymer, It comprises hydrophilic polymer. The antibacterial metallic component as used in the invention means that an antibacterial metallic component is held the surface and/or inside a polymer particle, as long as antibacterial properties are revealed [0007]. Mean particle diameter of a polymer particle may be 0.1 nm - about 100 micrometers. As said antibacterial metallic component, silver, copper, zinc, nickel, cobalt, chromium, etc. can be illustrated. A holding amount of an antibacterial metallic component is metal conversion, and is about 0.01 to 70% of the weight of the whole.

Said antimicrobial polymer can be manufactured by joining together chemically and making a functional group of hydrophilic polymer particles [0006]. In addition, the antimicrobial polymer particle is 1 to 50% of the weight of the whole [claim 6]. The metal can be in the form of a salt [0028] and the shape of the particle can be a rod or petaloid [0025], which read on the high aspect ratio greater than 2 as required by the instant claims since a tube or a rod have a length that is more than double its diameter. JP teaches also that the organic system antimicrobial agent is excellent in dispersibility over resin among said antimicrobial agents [0005], (the disclosure reads on ability of the additive to form discrete microparticles which is recited in instant claim 1). A ceramic carrier can be used [0040]. The polymer used can be polyurethane [0036]. An ammonium compound is comprised in the composition [0027]. Note that though JP did not use the ammonium salt for discoloration, same compounds have same properties and should accrue same function even if used for a different purpose. Note also that JP teaches combination of two or more sorts of metallic component [0026]. Regarding the requirement of claim 10 of hydrophilic polymer is having water absorption at equilibrium of at least about 20% by weight, it is noted that since JP used hydrophilic polyurethane required by the instant claims then the absorption at equilibrium should be the same especially that JP teaches that Various hydrophilic fragmentation and segments can be used as hydrophilic units such as units of vinylpyrrolidone [0009 and 00010]. Note that vinylpyrrolidone monomer is used by current application to render polyurethane into a hydrophilic polymer [see instant specification paragraph 0052] and as stated by Applicant in the declaration.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 10-22, 33-34, 48-49 and 55-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiharu et al. JP 11-222402 (JP) in view of Hagiwara et al. US 4775585 (Hagiwara) and further in view of and further in view of Makita et al. US publication 20010019727 (Makita).

JP is relied upon for the reasons set forth hereinabove. Note that JP disclosed the use of zeolites as known in the art.

JP did not teach the zeolite as a ceramic carrier of choice.

Hagiwara teaches a polymer article having antibacterial properties as well as a physical property similar to those of the polymer itself, which contains zeolite particles retaining metal-ions, which show an antibacterial effect at the ion-exchange sites of the zeolite particles. The zeolite particles are retaining one or more metal ions having a bactericidal property (col. lines 56-59). The polymer can be highly hydrophilic (col. 8, lines 7+) and the antimicrobial can be a metal salt of a metal having a bactericidal activity, such as silver, copper and zinc (col. 3, lines 12+). A particle size of the zeolite can suitably be selected depending on application fields. When granules or coarse fibers, the particle size may be in the range of a few microns to tens microns or even above several hundred microns (col. 4, lines 9+). Note that a fiber is inherently a high aspect ratio particle and that the ratio recited in instant claim 1 as greater than about 2 is also inherent in fibers because the fiber's length is usually -if not always- more than double its width or diameter. Note that the definition of fiber is as follows.

Fiber:

Materials: A thin, threadlike piece of any material.

"fiber". Academic Press Dictionary of Science and Technology (1992). Retrieved 28 August 2006, from xreferplus. http://www.xreferplus.com/entry/3104363.

The fibers or the yarns according to Hagiwara can be mix woven, cross woven or union knitted with fibers or yarns having no metal-zeolite to give an antibacterial fiber article with various feelings and functions. This disclosure reads on the limitations of instant claims 33, and 34.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate the hydrophilic polymer particles containing the metal ingredient because Hagiwara teaches that zeolite defined in the invention has an advantage that the reactivity thereof with a metal having a bactericidal activity, such as Ag, Cu, and Zn is high, and that its ion-exchange capacity is large and, therefore, a large amount of Ag.sup.+, Cu.sup.2+, or Zn.sup.2+ having a bactericidal activity can be retained in the zeolite.

Both references are deficient in disclosing the sodium nitrate dopant.

Makita teaches biocidal material which is excellent in chemical resistance and heat resistance and capable of continuously releasing a microdose of silver ion. The biocidal comprises an alkali metallic element. Among many compounds containing an alkali metal, carbonate, hydrogencarbonate and nitrate are preferable, and sodium carbonate, potassium carbonate and sodium nitrate are more preferable [0057]. The biocidal contains hydroxyapatite [0069] and active ingredient comprising silver ion, copper ion or zinc ion. The biocidal may contain an ammonium compound [0058].

Thus it would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a alkali metallic element such as sodium nitrate in the biocidal since the two inventions have the same endeavor and also because Makita teaches that the biocidal is excellent in chemical resistance and heat resistance and capable of continuously releasing a microdose of silver ion and can be recycled [0008].

Finally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of JP by choosing a ceramic carrier such as zeolite taught by Hagiwara and ad a sodium nitrate as taught by Makita because Hagiwara teaches many advantages of using zeolite and Makita described the antimicrobial compositions as having chemical resistance, heat resistance and have excellent antimicrobial effect. The expected result would be a rod or fiber shaped hydrophilic polymer particle retaining silver, zinc or copper and is comprised in a zeolite carrier.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,866,859. Although the conflicting claims are not identical, they are not patentably distinct from each other because '859 recites a composition of hydrophilic coat on an article which

contains a polysaccharide component (hydrophilic polymer), including a silver ion exchanged zeolite. Note that the claims of '859 do not recite particles, however, recites that the antibiotic ceramic component is dispersed within the polysaccharide which shows that the component is in the form of particles. Note also that '859 does not recite the water absorption at equilibrium, however, the claim does not exclude those percentages since it does not recited otherwise.

Claims 1-7, 10-22, 48-49 and 55-64 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 7357949. Although the conflicting claims are not identical, they are not patentably distinct from each other because Patent '949 is directed to the same subject matter recited in the instant claims. '949 recites antimicrobial additive comprising ion-exchange type antimicrobial agent comprising a ceramic carrier and metal ion and a hydrophilic polymer having the same water absorption at equilibrium and the same concentration of the antimicrobial agent. The polymer is hydrophilic polyurethane, the ceramic is zeolite. A discoloring ammonium is used, and the antimicrobial additive comprises a sodium nitrate dopant.

Claims 1-7, 10-15, 22, and 48-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 11/336699 in view of US publication Modak et al. 20010010016 (Modak).

'699 recites an antimicrobial additive dispersed in a hydrophobic matrix polymer. The additive is in the form of discrete particles of a hydrophilic polymer having

encapsulated therein or dispersed therein one or more particles of at least one antimicrobial metal such as silver, zinc or copper. The water absorption at equilibrium of the hydrophilic polymer is at least 20% and the concentration of the antimicrobial agent is the same as recited in the instant claims.

The difference between '699 and the instant claims is that the antimicrobial agent is dispersed in a hydrophobic polymer matrix.

Modak teaches polymeric medical articles comprising combinations of triclosan and silver-containing compounds. In a preferred embodiment, a hydrophobic polymer such as polyvinyl chloride may be used to create a hydrophobic matrix into which PVP and antimicrobial agents may be impregnated. Other useful hydrogels that may be used to promote enhanced antimicrobial efficacy [0049].

Thus, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to impregnate or coat the antimicrobial comprising silver with a hydrophobic polymer such as polyvinyl chloride to enhance the antimicrobial efficacy.

This is a provisional obviousness-type double patenting rejection.

Declaration under 37 CFR 1.132

The affidavit under 37 CFR 1.132 filed 6/21/2007 is insufficient to overcome the rejection of claims 1-7, 10-22, 33-34, 48-49 and 55-64 based upon 35 U.S.C as set forth in the last Office action because: the performed experiments are based on the particle size and its effect on the surface of the polymer into which it is incorporated. The experiments are also performed to show that the hydrophilic polymer wherein the additive particles enhances the antimicrobial effect of the additive.

In the current office action, the Examiner relied upon JP 11-222402 which teaches rods or petaloids (corresponding to high aspect ratio fiber and flake) teaches the same dimensions and the polymer used in the particle is hydrophilic especially that JP teaches the polyurethane and the vinylpyrrolidone units used to make the polyurethane hydrophilic as performed in the instant declaration and disclosed in the instant specification. In addition, the results obtained was obtained by using eh antimicrobial particles and the hydrophilic polymer which contained in a hydrophobic polymer matrix which is not the case in the instant claims. Instant claims do not recite a hydrophobic polymer matrix.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Pertinent Prior Art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is KURODA RYUZO et al. JP 10-067514 (Kuroda).

Kuroda teaches that to obtain a zeolite high in degree of crystallization, small in particle diameter, large in external specific surface area, by selecting the subject zeolite which is a laminar body having an average particle diameter and an aspect ratio of specific values. This zeolite is obtained by selecting the subject zeolite which is a laminar body having ≤0.5μm average particle diameter and ≥2 aspect ratio.

The disclosure shows that the aspect ratio ≥2 was known in the art as means to increase the external surface area of the zeolite which is in the instant case needed to enhance the release of the silver ions and consequently the antimicrobial effect.

The reference was not relied upon because the zeolite disclosed was used as a catalyst or adsorbent.

Response to Arguments

Applicant's arguments filed 11/10/2006 have been fully considered but they are not persuasive.

Anticipation in view of Hagiwara et al. US 4,775,585.

Rejection was withdrawn and thus the arguments render moot.

Obviousness over Hagiwara in view of Trogolo, Gibson, and further in view of Michael.

Trogolo, Gibson, and Michael have not been relied upon in the rejection and thus the arguments related to these references render moot.

- Regarding Hagiwara, applicant contends that the Examiner misinterpreted the claimed antimicrobial additive, the inorganic antimicrobial agent and the particle size of the antimicrobial agent. Applicant states "

- Applicant's attention is drawn to the language of the instant claims and how the claims were written. The Examiner cannot guess "what Applicant's are doing" as stated by Applicant in the arguments; the Examiner is tied to the claims language and to the extent of interpretation in light of the specification. In addition, it is noted that in view of relying upon Chiharu et al. JP 11-222402 which teaches the same particles, polymers and the ceramic carrier.

- Applicant simulates the instant subject matter with chocolate chips, dough and odors to discuss the rejection.

- The Examiner finds the simulation intended by Applicant is irrelative and confusing. In addition the arguments in such a way are not helping for the response because for example applicant states that "Hagiwara also allows for doughs that are hydrophilic or hydrophobic. With highly hydrophilic dough, Hagiwara indicates that the chocolate odor of those chocolate chips

....". Since Hagiwara does not disclose dough, odor or chocolate, it is not clear how the Examiner can respond to such arguments.

- Applicant argues the unexpected results presented by the inventor showing the importance of particle size and its effect on the surface of the polymer into which it is incorporated and the hydrophilic polymer which helps the additive particles to enhance the antimicrobial effect of the additive.

- As noted hereinabove, the primary reference which is closest to the prior art is now JP 11-222402 and not Hagiwara. Since JP teaches the same polymer used in the experiments performed, then the declaration is ineffective.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 9:00AM - 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618